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PREVENTION, PESTICIDES AND
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MEMORANDUM March 27, 2000

Subject: **Oxamyl RED Chapter:** EFED Response to Dupont's Error Corrections and Comments on Preliminary Chapters, Dated February 18, 2000

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We reviewed the comments provided by Dupont in their 2/18/00 comments on EFED's risk assessment chapter and have either corrected those errors identified by the registrant or have responded as to why no changes were needed. Only minor revisions are necessary to the EFED chapter; none of the corrections have resulted in a change to EFED's bottom line in its assessment and characterization of the environmental risk posed by the use of oxamyl.

This memo provides a point-by-point response to Dupont's February 18th gross error corrections and comments on the EFED Risk Assessment chapter. The numbers in our response below correspond to the numbers in Dupont's document. As requested, we are providing a separate "addendum to chapter" document, which identifies the corrections to the EFED chapter itself.

Dupont's Submission of Additional Environmental Fate Studies

Dupont submitted two additional studies on the environmental fate of oxamyl along with their "gross error correction" comments:

(A) Degradability and Fate of 1-14C Oxamyl in Water/Sediment Systems [Dupont ID AMR 3143-94; MRID 450453-05; Study completed December 4, 1995]

(B) Field Soil Dissipation of Oxamyl Following Application of Vydate L Insecticide [Dupont ID AMR 2889-93; MRID 450453-04; Study completed March 28, 1996]

A precursory review of the results indicate that neither study will change the bottom-line conclusions in EFED's risk assessment. For this reason, a detailed study review was not conducted as a part of this response, and no determination was made as to whether the studies would be considered acceptable/unacceptable/supplemental according to guideline standards. Both of these studies were conducted several years ago (1995 and 1996) and the registrant had sufficient time and notice to submit these prior to the error correction phase. A Data Evaluation Report (DER) on these studies can be prepared as a part of the RED follow-up, but should not be a reason to delay the RED process. For future REDS, EFED encourages the registrant to submit such studies during the initial review process rather than during the "error correction" period.

Dupont Comments on the "Tier II EEC Chapter"

This memo, dated October 28, 1999, to HED is incorrectly identified as a separate chapter in the RED. The memo provides HED with estimated concentrations of oxamyl in drinking water and provides documentation of the modeling and monitoring data that went into the assessment and how the concentrations were derived. The drinking water assessment portion of the EFED chapter incorporates the pertinent information, along with the data and documentation, and should be used rather than this memo.

No changes are recommended here since they will be addressed in the appropriate sections of the EFED chapter.

Dupont Comments on Gross Errors in the EFED Chapter

1. Correct the typo identified on p. 2 of the EFED chapter: change "oxaime" to "oxime".

2. Dupont's comment that a shorter half-life be used for aquatic metabolism in modeling is not, strictly, a "gross error" correction since EFED used the best available data in this risk assessment. The study submitted by the registrant with their error comments was completed in 1995 and could have been submitted before EFED began this risk assessment. In the "Additional Comments" section that follows (p. 23 of 23), Dupont notes that, given corrections for hydrolysis, the half-life due to aquatic metabolism would be approximately 7 days. However, a precursory scan of the data indicates that the pH of the system increased (up to pH 8.3) as the study continued, so that hydrolysis may have had a greater impact than estimated by Dupont's calculations. Even if the study was considered supplemental, the results of this study would not change the bottom-line risk assessment because:
    a. The inclusion of the hydrolysis half-life (8 days at pH 7) and the aqueous photolysis half life (11 days) in the models does simulate degradation of oxamyl in water; the addition of a 7-day metabolism half-life will not appreciably change the estimated environmental concentrations reported by existing modeling.
    b. The existing model estimates do not raise concerns for aquatic impacts.

c. Since the drinking water assessment is based on both modeling and monitoring, the estimated concentration of oxamyl in surface water sources of drinking water would not change (the Drinking Water Exposure Assessment already notes that oxamyl is not expected to persist and adjusted the modeled concentrations, based on available monitoring data, to reflect that).

3. References have been added. The citations identified with "EFGWB One-Liner" came from the 1996 version of EFED's oxamyl risk assessment, and are intended to coincide with the data reported by the Product Chemistry folks; where these differ, substitute the data reported in the Product Chemistry section of the RED (along with the appropriate MRID) so that no discrepancies exist. The Montgomery (1991) reference has been used to supplement our information and those values (side-by-side with the reference) should remain. Since EFED reported the solubility in scientific notation (2.8×10^5 mg/L) to two significant figures, no revision is necessary. 2.8×10^5 is not different from 282,000.

4. The MS field dissipation study Dupont refers to on this point was completed in March 1996, but was not submitted until February 2000. In the cover letter for their comments, Dupont notes that the study supports "the Agency's assumptions about oxamyl." Since this would not change EFED's bottom-line conclusions for its risk assessment, no changes will be made to EFED's chapter.

5. A review of the NC prospective ground-water monitoring study shows that concentrations of oxime as high as 4.5 ug/l (in Well 7) were detected; concentrations of oxime between 1 and 2 ug/l occurred for long periods of time in the study. In at least one well (well 7), the concentration of oxime was greater than 3 ug/l for at least one sampling period (60 days). EFED used this as a screening-level concentration. Additional refinements, calculating running-time averages over toxicologically-significant intervals, would be made only if the estimated oxime concentration exceeded the drinking water level of comparison. Otherwise, EFED notes that oxime passed the screen and no further work is necessary.

6. EFED did generate an electronic copy of Figure 1, which overlaid the USGS NAWQA study units with the major crops on which oxamyl is used. On further examination, we noted that this figure best illustrates the overlap when produced in color; details are lost in black-and-white printing and photocopying. Since the point can just as easily be made by noting the overlap in the comparison, and referencing the sources of the original maps, we provided an alternate paragraph which removes reference to Figure 1.

7. Correct the typo identified on this point.

   EFED checked the STORET data and found that the site with 10 detections was indeed Linden, WA, and not Whatcom Co, CA. This will be corrected.

8. The RED document provided a citation for the report on the bee kills, including an incident number and a year. EFED believes this is sufficient documentation for that incident. Since the original wording of that paragraph in the RED may have been

misunderstood, we've recommended alternate wording.

9-11. Revisions will be made as noted.

12. The section which includes Table 9 has been revised using an application rate of 1.25 lb ai/A with incorporation for tomatoes.

13. Dupont states that sufficient detailed documentation was not provided for the PRZM/EXAMS EECs reported in Tables 10-13. The chapter refers the reader to Appendix C for details of the modeling. That appendix provides the chemical-specific inputs, site and weather information used, and the specific PRZM input files for each of the modeled crops. This should provide sufficient detail to duplicate the modeling. No changes are necessary.

14. Three additional citations have been added to the "References with no MRID #" section.

15. Dupont provided the "current/correct/acceptable" chemical names for the structures in appendix A. We used the CAS names for the 2 degradates (which are the same as listed in Dupont's comments), but didn't include the name for oxamyl. Our suggestion is to add the CAS name for oxamyl to be consistent with the other structures. The remaining items (IUPAC name and CAS No) can be inserted or left out.

16. Additional references have been added to the table in Appendix C. The issues raised here have already been addressed in point number 3.

17. According to Dupont, their label for oxamyl use on pineapples provides a maximum single application rate of 4 lb ai/A and a maximum seasonal rate of 8 lb ai/A. We used the rates which were available at the time, with single rates of 2 lb ai/A and seasonal rates of 12 lb ai/A. Changes in label rates occurred after these intial Tier 1 screens were run. EFED did NOT rely on these model runs in its risk assessment. A pineapple scenario was not evaluated for ecological risk assessment; the drinking water assessment considered both PRZM/EXAMS modeling (on cotton, apples, and carrots) and monitoring data, and provided an estimated oxamyl concentration in surface water sources of drinking water based on monitoring. The ground-water assessment for drinking water was based on monitoring data. Since the assessment was later done using a higher tier approach the results of the GENEEC and SCI-GROW modeling was not used. We are therefore deleting these first tier results and leaving only the modeling and monitoring information that actually was used.

18 The Terrestrial EEC Calculations at the end of Appendix D were modified to (a) reflect the correct soil application rate for tomatoes, and (b) to clear up the confusion the registrant identified in the calculations.

Additional Comments on the EFED Chapter

As noted earlier, Dupont refers to two older studies – a 1995 aquatic metabolism study and a 1996 field dissipation study – that were only submitted on 2/18/2000 along with the error correction document. EFED has not conducted a review of these studies. Based on the registrant's interpretation of the results, neither study would change the bottom-line conclusions in EFED's risk assessment.

EFED notes that the registrant's calculations on the estimated half-life from microbial breakdown is based on the assumption that the pH of the system remained constant at 7. Data in the study indicate that the pH increased to at least 8.3 during the study. As the fate data show, the rate of hydrolysis of oxamyl increases as the pH increases. This suggests that hydrolysis may have had a greater role in the degradation of oxamyl than estimated by the registrant.